Supreme Court, U.S.
FILED
DEC 3 - 2004
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(3)

No. 04-607

IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS (D/B/A LABCORP),

Petitioner,

v.

METABOLITE LABORATORIES, INC., AND COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF FOR RESPONDENTS IN OPPOSITION

MARK A. PERRY
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue N.W.
Washington, D.C. 20036
(202) 955-8500

GLENN K. BEATON
Counsel of Record
J. GREGORY WHITEHAIR
GIBSON, DUNN & CRUTCHER LLP
1801 California Street
Denver, Colorado 80202
(303) 298-5700

Counsel for Respondents

QUESTION PRESENTED

Whether both lower courts correctly sustained the jury's factual finding that petitioner willfully induced infringement of respondents' patent.

RULE 29.6 STATEMENT

Respondents in this case are Competitive Technologies, Inc. and Metabolite Laboratories, Inc. Neither has any parent corporations. No publicly held company owns ten percent or more of the stock of either respondent.

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BRIEF FOR RESPONDENTS IN OPPOSITION

Respondents Metabolite Laboratories, Inc. and Competitive Technologies, Inc. respectfully submit that the petition for a writ of certiorari should be denied.

STATEMENT

After a jury trial, petitioner LabCorp was held liable for willfully inducing infringement of United States Patent No. 4,940,658, and ordered to pay damages to respondents. The Federal Circuit affirmed.

1. The '658 patent claims methods for detecting deficiencies in the human body of cobalamin (vitamin B_{12}) and folate (folic acid), which may cause serious illnesses if not treated. Pet. App. 2a. The inventors discovered that elevated levels of the amino acid homocysteine could serve as a marker for a deficiency in either cobalamin or folate. *Ibid.* Claim 13 of the '658 patent recites:

> A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> assaying a body fluid for an elevated level of total homocysteine; and
>
> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

Id. at 3a (quoting '658 patent, col. 11, ll. 58-65).

Respondents licensed petitioner (and many others) to perform total homocysteine assays for the purpose of detecting cobalamin or folate deficiencies. Pet. App. 3a. "But in 1998, LabCorp switched to a total homocysteine assay developed by Abbott Laboratories . . . and discontinued

royalty payments to Metabolite for total homocysteine assays." *Ibid.*

Respondents sued petitioner for infringing the '658 patent. Pet. App. 3a. The jury found the patent to be valid, found petitioner liable for willfully infringing it, and assessed damages. *Id.* at 4a. The district court sustained the jury's findings (*ibid.*), and the court of appeals affirmed.

2. The court of appeals first construed the claim term "correlating." Pet. App. 7a. The court noted that petitioner had "urged the district court to construe 'correlate' according to its dictionary definition as a verb meaning 'to establish a mutual or reciprocal relation of' an elevated level of homocysteine," and that the district court adopted this construction. *Id.* at 8a. The court of appeals concluded that the claim language, the specification, and the prosecution history all supported this construction: "In sum, the specification and prosecution history confirm that the claim language 'correlating,' in the understanding of one of ordinary skill in this art field at the time of invention, includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency." *Id.* at 12a. The court refused to allow petitioner, on appeal, "to change its claim construction position to read out the reciprocal relationship that it initially urged."

The court of appeals next concluded that substantial evidence supported the jury's verdict that petitioner willfully induced infringement of the '658 patent. The court noted that the inducement statute (35 U.S.C. § 271(b)) "requires proof of intent to induce infringement," and held that "[t]he record contains such evidence of intent." Pet. App. 14a-15a. Petitioner's "own publications ... promote total homocysteine assays for detecting cobalamin/folate deficiency" and "state that elevated total homocysteine

correlates to cobalamin/folate deficiency." *Id.* at 15a. "Because '[i]ntent is a factual determination particularly within the province of the trier of fact,'" the court declined to reverse the jury's verdict on induced infringement. *Ibid.* (citation omitted).

Finally, the court of appeals rejected petitioner's challenges to the validity of the '658 patent. The court concluded that claim 13 is not indefinite because "the claim construction exercise at the trial court produced a discernible and clear meaning" of the "correlating" step. Pet. App. 16a. The court concluded that the written description requirement was met because both the patent examiner and petitioner's "own expert and employees understood the meaning of 'correlating.'" *Id.* at 17a. And the court held that "[t]he specification also shows that the patentee enabled the claimed invention." *Ibid.*

ARGUMENT

The decision below is correct and does not conflict with any decision of this Court, the Federal Circuit, or any other court of appeals. Further review is therefore not warranted.

1. Petitioner's principal argument is that the Court should grant review to resolve an asserted "conflict" within the Federal Circuit's decisions regarding the intent element of induced infringement. Pet. 12. To the extent it exists at all, this "conflict" is not implicated on the facts of this case.

Petitioner contends that "[a] principal controversy underlying this case stems from two inconsistent Federal Circuit opinions issued over a decade ago ...." Pet. 12 (citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544 (Fed. Cir. 1990), and *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464 (Fed. Cir. 1990)). It is far from clear that these two authorities are, in fact, in conflict. *Hewlett-Packard* deals with ordinary infringement by inducement, while *Manville* deals with the special

circumstance of a corporate officer being held liable for infringement by inducement for directing the infringing acts of the corporation. Even in the narrow, and inapplicable, *Manville* scenario, at least one of the commentators cited by petitioner admits himself that the conflict may be largely in the minds of commentators. *See* Michael N. Rader, Toward a Coherent Law of Inducement to Infringe: Why the Federal Circuit Should Adopt the Hewlett-Packard Standard for Intent Under § 271(b), 10 Fed. Circuit B.J. 299, 324 (2000) ("Nonetheless, commentators have not given up on the *Manville Sales* formulation.").

In any event, there is no reason to believe that the Federal Circuit is incapable of resolving any conflict that may exist in its precedents on this point. *Wisniewski v. United States*, 353 U.S. 901, 902 (1957) ("It is primarily the task of a Court of Appeals to reconcile its internal difficulties").

Petitioner fails to inform the Court that this so-called "principal controversy" over infringement by inducement that forms the centerpiece of its certiorari request has never before been asserted in the protracted history of this litigation. To the contrary, petitioner cited *both* of the supposedly conflicting decisions in the court of appeals as articulating the *correct*, and apparently equivalent, standard for intentional inducement of patent infringement. LabCorp's Fed. Cir. Br., Opp. App. A, *infra* at 2a. ("[I]n any event, LabCorp cannot be liable for inducing infringement because CTI did not establish that LabCorp specifically intended that physicians use single homocysteine tests to determine deficiencies of cobalamin or folate." (citing both *Hewlett-Packard* and *Manville*) (emphasis in original)). The "conflict" on which petitioner relies therefore has not been properly preserved for this Court's review. *See, e.g., Taylor v. Freeland & Kronz*, 503 U.S. 638, 646 (1992) ("ordinarily, this Court does not decide questions not raised or resolved in

the lower court[s]") (quoting *Youakim v. Miller*, 425 U.S. 231, 234 (1976) (per curiam)); *United States v. Lovasco*, 431 U.S. 783, 788 n.7 (1977).

More importantly, resolving the "conflict" asserted by petitioner would have no impact on the jury's verdict. Petitioner contends that "under the *Manville Sales* analysis, a party like LabCorp could only be liable for inducement to infringe if it *knew or should have known its acts were inducing actual infringement.*" Pet. 14 (emphasis added). The jury in this case was instructed on precisely this test:

> To show infringement of claim 13 by inducement, plaintiffs must prove by a preponderance of the evidence that someone has directly infringed claim 13. If there is no direct infringement of claim 13 by anyone, defendant has not induced infringement. If you find that someone has directly infringed claim 13, it is not necessary to show that defendant LabCorp itself has directly infringed, if plaintiffs prove by a preponderance of the evidence that LabCorp actively and knowingly aided and abetted that direct infringement. Plaintiffs-must show that LabCorp *knew or should have known that its actions would induce actual infringement.* LabCorp cannot be liable for inducing infringement if it had no reason to be aware of the existence of the patent.

Jury Instruction No. 21, Opp. App. B, *infra* at 4a. This jury instruction is drawn from the model instructions published by the American Intellectual Property Law Association,[1] but

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[1] *See* AIPLA Model Jury Instruction on Inducing Infringement, *available at* http://www.aipla.org/Content/ContentGroups/Publi-

with one critical difference. The jury instruction in this case *omits* the phrase, found in the AIPLA model jury instruction, "actually intended to cause the acts that constitute direct infringement and that LabCorp" just before the language emphasized in the quote above. The jury instructions actually used in this case thus contain the stringent *Manville* standard now urged by petitioner, and omit the arguably less stringent *Hewlett-Packard* standard.

The rule reflected in the jury instruction is thus the same as petitioner now urges this Court to adopt, and a reversal with remand would make no difference. Consequently, accepting the Petition would lead this Court impermissibly to render a mere advisory opinion. *See, e.g., Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477-79 (1990) (federal courts lack jurisdiction to adjudicate claims where the complaining party lacks a "personal stake in the outcome" or a "specific live grievance").

Petitioner stipulated to the jury instruction quoted above, understandably because it sets forth the more stringent *Manville* formulation that it urges on this court. Petitioner never appealed that instruction to the court of appeals. Therefore, the legal rule embodied in the instruction is not reviewable in this Court. *City of Springfield v. Kibbe*, 480 U.S. 257, 258-59 (1987).

This case is a particularly poor candidate for retooling the intent element of inducement given that the jury found by clear and convincing evidence that LabCorp's infringement was willful. LabCorp did not appeal that factual

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cations1/Guide_to_Model_Patent_Jury_Instructions.htm#Claim Construction6.

determination. Pet. App. 24a.[2] Unless this Court is prepared to review a fact finding, upon which no appeal was taken, LabCorp's argument to this Court must reduce to the following: its infringement was willful but unintentional.

To the extent petitioner is contending that the evidence was insufficient to support the jury's finding of inducement, that factual issue was resolved against petitioner by both the court of appeals and the district court. Further review in this Court is thus unwarranted. *See, e.g., Graver Mfg. Co. v. Linde*, 336 U.S. 271, 275 (1945) ("A court of law, such as this Court is, rather than a court for correction of errors in fact finding, cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error.").

2. Petitioner next claims that the court of appeals improperly construed the "correlating" step to encompass a reciprocal as well as a mutual relationship between homocysteine levels and vitamin deficiencies.[3] Pet. 20-23. Petitioner's contention is that the "correlating" step should instead be construed to cover a positive result but not a negative result. In rejecting that attack, the Federal Circuit applied well-settled rules of claim construction, looking first to the ordinary meaning of the terms at issue and then to the specification and file history of the patent. The Federal Circuit also noted correctly that the record shows that petitioner itself proposed the very construction that it now disputes: That the "correlating" step refers to a "mutual" or a

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[2] LabCorp did appeal the district court's award of enhanced damages for the willful infringement. The court of appeals unanimously upheld that award. Pet. App. 27a & 28a.

[3] Even the lone dissenter in the court of appeals, while apparently disputing the jury's application of the claim construction, stated "I too do not disagree with the district court's construction of the terms 'elevated' and 'correlating.'" Pet. App. 30a.

"reciprocal" relationship, a proposal that the district court adopted and the Federal Circuit affirmed. The mutual relationship applies to one test outcome, and the reciprocal relationship applies to the other test outcome. The court of appeals observed "that the perfect symmetry between 'mutual or reciprocal' and 'presence or absence' shows that the district court correctly placed the term 'correlating' in its proper context with its proper meaning." Pet. App. 11a.

This patent-specific issue of claim construction was thoroughly vetted in both the district court and the court of appeals. The majority of the court of appeals agreed with the district court – and, indeed, with the construction that petitioner had previously advanced in the district court – that the construction urged by petitioner on appeal was unduly narrow and was not consistent with the claim language, the ~~specification, or~~ the prosecution history. This Court does not sit to review such case-specific determinations. *Cf. United States v. Johnson*, 268 U.S. 220, 227 (1925).

3. Petitioner also contends that the patent is invalid. Pet. 23-26. But petitioner's own witnesses and medical expert testified that they had no difficulty deciphering the meaning of the claim at issue. Nine of petitioner's competitors pay royalties on this patent with no difficulty in deciphering it. For six years, petitioner paid too, until a LabCorp technician with no training in patent law unilaterally decided to stop paying in an effort to cut costs. That was a (misguided) business decision, not evidence of invalidity.

Petitioner's validity argument, like the claim construction argument, does not extend beyond the specific patent at issue in this case. The court of appeals and the district court both rejected petitioner's invalidity arguments on the basis of the evidence submitted to the jury. There is no reason for this Court to revisit that fact-specific determination. *See Graver Mfg.*, 336 U.S. at 275 (declining

to reconsider fact-based validity determinations made by both lower courts).

4. Finally, petitioner predicts dire consequences for the future of the Nation's healthcare if the decision below stands. Pet. 2, 26-30. But petitioner's assertion that the Federal Circuit has effectively allowed a monopoly on a basic scientific fact and enjoined physicians from engaging in "thought processes" is mere hyperbole.[4] Not a single physician has been enjoined, sued or even threatened with suit, and none will be. The method patent at issue cannot be infringed by a physician's mere thought processes, because the patent requires a further distinct and physical step: the step of assaying for total homocysteine. Unlike the "author of a medical textbook" to whom petitioner compares itself (Pet. 18), petitioner performs that physical step and thereby completes the act of induced infringement. The jury concluded that petitioner is liable for violating the law in this regard. The district court agreed, the court of appeals panel agreed, and the court of appeals *en banc* unanimously denied the petition for rehearing. Nothing in that factbound determination implicates important legal issues of general applicability or warrants review by this Court.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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[4] Petitioner's warning of "nationwide confusion" over this case (Pet. 2) is similarly hysterical. As of the date of this Response, the case has not attracted a single article or commentary, and no amicus briefs were filed with the court of appeals or this Court.

MARK A. PERRY
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue N.W.
Washington, D.C. 20036
(202) 955-8500

GLENN K. BEATON
Counsel of Record
J. GREGORY WHITEHAIR
GIBSON, DUNN & CRUTCHER LLP
1801 California Street
Denver, Colorado 80202
(303) 298-5700

December 3, 2004.

APPENDIX

APPENDIX A

United States Court of Appeals for the Federal Circuit

03-1120

METABOLITE LABORATORIES, INC., and
COMPETITIVE TECHNOLOGIES, INC.,

Plaintiffs-Appellees,

- v.

LABORATORY CORPORATION OF AMERICA
HOLDINGS (doing business as LabCorp),

Defendant-Appellant.

Appeal from the United States District Court for the
District of Colorado in 99-Z-870,
District Judge Zita L. Weinshienk

CORRECTED BRIEF FOR APPELLANT LABORATORY CORPORATION OF AMERICA HOLDINGS

Of Counsel:

JOHN P. HIGGINS
ALSTON & BIRD, LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, North Carolina 28280
(704) 444-1000

JONATHAN S. FRANKLIN
CATHERINE E. STETSON
HOGAN & HARTSON L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109
(202) 637-5766

Counsel for Appellant Laboratory
Corporation of America Holdings

February 19, 2003
(Corrected Brief filed March 12, 2003)

* * * [34]

4. LabCorp Did Not Induce Infringement.

Without the necessary proof of direct infringement, CTI's claim of induced infringement fails. See supra at 25. But in any event, LabCorp cannot be liable for inducing infringement because CTI did not establish that LabCorp [*35] specifically intended that physicians use single homocysteine tests to determine deficiencies of cobalamin or folate. See Hewlett-Packard Co., 909 F.2d at 1469, 15 USPQ2d at 1529 ("proof of actual intent to cause the acts which constitute infringement is a necessary prerequisite to finding active inducement"); Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553, 16 USPQ2d 1587, 1594 (Fed. Cir. 1990) (alleged active inducer "must be shown * * * to have knowingly induced infringement").

The trial evidence overwhelmingly demonstrated that LabCorp intended for single homocysteine tests to be used to screen for risk of heart disease, rather than to determine deficiencies of cobalamin or folate. As noted, Dr. Allen himself observed that it would not be good medical practice to use a single homocysteine test to determine vitamin deficiencies, A7950, and LabCorp's Director of Toxicology agreed. A7971.

LabCorp's own materials make the same point. The entry for the single homocysteine test in LabCorp's Directory of Services expressly refers physicians to the royalty-bearing panel test to determine deficiencies in folate. A8501, A8505. The Directory's entry for the panel test, in turn, does not refer physicians to the single homocysteine test. A8499. LabCorp's patient report for the single homocysteine test likewise refers physicians to the panel test to determine vitamin deficiencies, specifically cautioning that the single test "is [*36] intended to be used as an independent risk factor for vascular disease and is NOT for the diagnosis of folate or

cobalamin deficiency." A8446. LabCorp beyond doubt lacked specific intent to cause infringement.

* * *

[*63]

Respectfully submitted,

/s/
Jonathan S. Franklin
Catherine E. Stetson
HOGAN & HARTSON L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109
(202) 637-5766

Counsel for Appellant Laboratory Corporation of America Holdings

Of Counsel:

John P. Higgins
ALSTON & BIRD, LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, North Carolina 28280
(704) 444-1000

February 19, 2003
(Corrected Brief filed March 12, 2003)

APPENDIX B

JURY INSTRUCTION NO. 21

To show infringement of claim 13 by inducement, plaintiffs must prove by a preponderance of the evidence that someone has directly infringed claim 13. If there is no direct infringement of claim 13 by anyone, defendant has not induced infringement. If you find that someone has directly infringed claim 13, it is not necessary to show that defendant LabCorp itself has directly infringed, if plaintiffs prove by a preponderance of the evidence that LabCorp actively and knowingly aided and abetted that direct infringement. Plaintiffs must show that LabCorp knew or should have known that its actions would induce actual infringement. LabCorp cannot be liable for inducing infringement if it had no reason to be aware of the existence of the patent.

If you find that someone has directly infringed claim 13 and that LabCorp knew or should have known that its actions would induce direct infringement, you may find that LabCorp induced another to infringe claim 13 if it provided instructions and directions to perform the infringing act through labels, advertising or other sales methods. You may find that LabCorp induced infringement even if there is an express warning against the infringement, if the material containing the warning nonetheless invites the infringing activities under the circumstances. You may find that LabCorp induced infringement by supplying the components that are used in an infringing method or apparatus with the knowledge and intent that its customer would directly infringe by using the components to make, use or sell the patented invention.